



QUALITY ASSURANCE PROGRAM DESCRIPTION

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Approved by:

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Date



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QUALITY ASSURANCE COMMITMENT (POLICY)

Foster Wheeler Environmental Corporation (FWENC) and its managing subcontractor EnergX TN, LLC (EnergX) are committed to the concept of Total Quality Management. This total quality management philosophy focuses on the continual improvement of organizational processes and promotion of quality consciousness in day-to-day performance.

Total Quality Management demands that FWENC, EnergX and our client, the U.S. Department of Energy (DOE), share a vision for the Transuranic (TRU) Waste Processing Center (TWPC). On this site our shared mission statement is:

Provide cost-effective, safe, environmentally-compliant treatment and disposal of the TRU Waste located on the Oak Ridge National Laboratory (ORNL) reservation.

Our client sought "innovative solutions" and "sound, workable practices" in the evaluation and selection of FWENC and EnergX for operation of the TWPC.

The FWENC and EnergX quality assurance approach involves proven practices and a strong emphasis on line management and worker implementation. The program outlined herein has been specifically tailored to include the functional elements of an integrated safety management system and performance assurance to best accomplish the TWPC mission and satisfy our client.

This Quality Assurance Program Description (QAPD) outlines the TWPC approach to applying these solutions and practices in a way that provides an objective basis for confidence that we successfully achieve the TWPC requirements for quality products and services, including compliance with applicable regulatory requirements.

Personnel perform their assignments at TWPC according to the provisions of this QAPD.

TRU Waste Processing Center
Executive Vice-President and General Manager



1.0 INTRODUCTION

1.1 Purpose

This document defines Foster Wheeler Environmental Corporation (FWENC's) Quality Assurance Program (QAP) for the Transuranic (TRU) Waste Processing Center (TWPC). The TWPC operates under Department of Energy Oak Ridge Operations (DOE ORO) contract number DE-AC05-98OR22516. This Quality Assurance Program Description (QAPD) serves the following purposes:

- It includes FWENC's quality assurance commitment (policy) for the TWPC
- It documents the TWPC's QAP plan and implementation strategy
- It identifies the strategy for assuring quality
- It serves as the description of the TWPC's QAP and implementation strategy for submittal to DOE for approval under DOE Order 414.1C and Title 10 Code of Federal Regulations (CFR) 830.122
- It identifies TWPC quality assurance requirements and the response to these requirements, but it does not establish new requirements

Quality assurance activities include plans and actions that provide confidence in the quality of the final product and the process that produced it. These activities are carried out by a combination of TWPC participants, including those involved in planning, performing, and assessing work and work results. These planned activities are referred to as the TWPC QAP.

The QAP encompasses activities and controls applied to the TWPC, from initial activities, through facility implementation, and successful waste processing and certification. Satisfying client requirements, regulatory commitments, and waste acceptance programs at repositories shape and result in refinements to the QAP. As such, it addresses the following:

- Creating a framework, within the approved boundaries of which the TWPC can operate compliantly and with reasonable flexibility
- Operating and modifying as needed, the TWPC to meet DOE ORO contract requirements
- Certifying the waste products to disposal site criteria
- Transporting the waste product by approved shipping methods
- Delivering the waste products for storage in the event that access to disposal facilities is not available



The QAP implements a broad range of plans and actions specifically applied with the appropriate and commensurate level of assurance, to achieve the TWPC mission. This integrated set of plans and actions incorporate cost-effective, risk-based approaches matched to the DOE ORO contract requirements. Finally, this QAP ensures that subcontractors and suppliers work and perform in a manner that is consistent with the TWPC's commitments and DOE ORO requirements.

1.2 Transuranic (TRU) Waste Processing Center (TWPC) Scope

The current TWPC scope of work involves designing, licensing/permitting, constructing, testing, and operating a facility on the Oak Ridge Reservation to retrieve, treat, and package Low-Level Waste (LLW), Mixed Low-Level Waste (MLLW) and TRU waste for eventual disposal at licensed land disposal facilities. In DOE's terminology, the TWPC is considered a Category 2 Non-Reactor Nuclear Facility. The TWPC scope excludes characterization and certification of TRU waste to Waste Isolation Pilot Plant (WIPP) acceptance criteria, which will be performed by the Central Characterization Project (CCP) under a separate DOE contract. The TWPC scope includes packaging and treatment of low-level and mixed waste and transporting it to an appropriate permanent disposal facility. In the event the appropriate DOE disposal site is not available for disposal of the treated waste, DOE will temporarily store the treated TRU waste at a site to be selected.

The waste types to be treated by the TWPC may be generated at ORNL site or other DOE facilities. These waste types include:

- Remote Handled (RH) tank wastes (Sludge and Supernate) presently stored in the Melton Valley Storage Tanks or other tanks on the Oak Ridge Reservation
- RH solid wastes (debris) presently stored in facilities on the Oak Ridge Reservation
- Contact Handled (CH) solid wastes (debris)

The treated waste is prepared, packaged, and documented in accordance with the waste acceptance criteria and other requirements of the appropriate disposal facility.

1.3 Application

Activities relating to the TWPC contracted scope of work are performed in accordance with this QAP. For each work item or activity, requirements are selectively applied based on the item or activity's importance to quality, health and safety, potential risk to the environment, or significance in meeting waste acceptance objectives. Therefore, the QAP is more rigorously applied to the TWPC work that is directly related to nuclear safety, radioactive waste operations, and waste acceptance.

The scope and rigor of the individual assuring actions that collectively comprise the QAP, are based on the TWPC's technical approach, its simple, proven technology, and a well-defined operating envelope that is implemented by well-trained, experienced performers and managers. Most of the assuring actions are the responsibility of line



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managers and workers. This approach to quality assurance emphasizes that TWPC personnel do the job right the first time by integrating the majority of assuring and controlling actions into the planning and work processes. Program-level assuring actions necessary to strengthen this approach are carried out by line managers and staff specialists in planning, quality, management, environmental, safety, health, and similar disciplines.

A process for selectively applying the QAP to these quality achieving work activities using a risk-based system is further described in Section 4.1.1.8.

2.0 QUALITY ASSURANCE REQUIREMENTS

The TWPC QAP is designed to implement each of the quality assurance requirements prescribed in the FWENC contract for operating the TWPC. This includes implementing requirements defined in Figure 2.0-1 for three major categories of work: (1) Nuclear Safety Related Activities, (2) Radioactive Waste Operational Activities, and (3) Waste Characterization, Acceptance and Transportation Activities. The basic quality assurance requirements applicable to these work activities are DOE Order 414.1C, Quality Assurance, and the quality assurance requirements of the *Price-Anderson Amendments Act (PAAA)* of 1988 as codified in 10 CFR 820, 830 and 830.122. Additionally, ASME NQA-1, *Quality Assurance Program Requirements for Nuclear Facilities* applies as directed by the waste certification and acceptance requirements of the final waste repositories.

The QAP integrates with the TWPC Safety Management System (SMS). The SMS describes a systematic integration of controls and assurances into the management and work processes of the TWPC. The QAP works in an integrated manner with the SMS to apply assuring activities in the execution of the processes that ensure work is defined and executed in a safe and compliant manner. This integration of the two programs is highlighted in the crosswalk in Appendix A to the Program criterion of 10 CFR 830.122.

The requirements of DOE Order 226.1, "Implementation of Department of Energy Oversight Policy," are addressed throughout the QAPD. The contractor assurance system, as described in the QAP, includes environment, safety and health, safeguards and security, emergency management, and cyber security. The contractor assurance system includes self-evaluations of compliance with DOE Order 226.1, applicable laws, regulations, national standards and DOE directives, and is implemented through approved TWPC procedures.

Prior to retrieval and treatment of a waste type, a more definitive set of QAP activities for waste acceptance is developed under the umbrella of the overall TWPC QAP to describe how the TWPC meets the additional quality assurance requirements applicable to the characterization and acceptance criteria of that waste type. Figure 2.0-2 shows how these QAP defining documents are related.



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Nuclear Safety Related Activities		Radioactive Waste Management Operational Activities		WIPP Waste Acceptance Activities (by CCP)						NTS Waste Acceptance Activities	
				Waste Characterization		Waste Certification		Transportation Packaging		Waste Certification	
Requirement(s)	Rev	Requirement(s)	Rev	Requirement(s)	Rev	Requirement(s)	Rev	Requirement(s)	Rev	Requirement(s)	Rev
<ul style="list-style-type: none">10 CFR 830	NA	<ul style="list-style-type: none">DOE O 435.110 CFR 835DOE 5480.19	NA NA NA	<ul style="list-style-type: none">WIPP TRU Waste Analysis Plan	8Jul05	<ul style="list-style-type: none">WIPP CH Waste Acceptance Criteria	3, 25Apr05	<ul style="list-style-type: none">(Payload Control)		<ul style="list-style-type: none">NTS Waste Acceptance Criteria	NA
<ul style="list-style-type: none">DOE Order 414.1C	NA	<ul style="list-style-type: none">ASME NQA-1 (Basic & Supplements)	NS					<ul style="list-style-type: none">CH TRAMPAC	Apr03	<ul style="list-style-type: none">DOE Order 435.110 CFR 830.122	NA NA
								(Usage Requirements)			
								<ul style="list-style-type: none">10 CFR 171	NA		
								<ul style="list-style-type: none">49 CFR 173	NA		
								<ul style="list-style-type: none">49 CFR 178	Jul03		
								<ul style="list-style-type: none">DOE TRUPACT II Certificate of Compliance, NRC Document, No.71-9218			
								<ul style="list-style-type: none">CH Packaging Operations Manual	Sep03		
								<ul style="list-style-type: none">CH Packaging Maintenance Manual	Jan02		

NS = Not Specified

NA = Not Applicable (e.g., current law)

TBD = To be determined when certification activities

Figure 2.0-1
TRU Waste Processing Center
Quality Assurance Requirements



3.0 OBJECTIVES

The objectives of developing and implementing this QAP are to meet DOE requirements for quality by:

- Assuring that an appropriate level of quality is attained to accomplish the overall TWPC contracted scope of work commensurate with DOE's responsibility for protecting the worker, the environment, the public's health and safety, and for efficient and effective use of national resources.
- Complying with applicable federal, state, and local laws, regulations, and requirements, and other requirements imposed by the DOE contract.

4.0 PLANNED CONTROL ACTIONS

The QAP describes assuring activities that relate to the ten criteria of 10 CFR 830.122 and DOE Order 414.1C. The activities are grouped under the three functional categories of management, performance, and assessment. The QAP is implemented using the controls and documents listed in Appendix A. Implementing documents are prepared or modified as necessary to implement TWPC contracted requirements and the commitments based on the activities. Appendix A reflects the current activities at the implementation date of the QAPD.

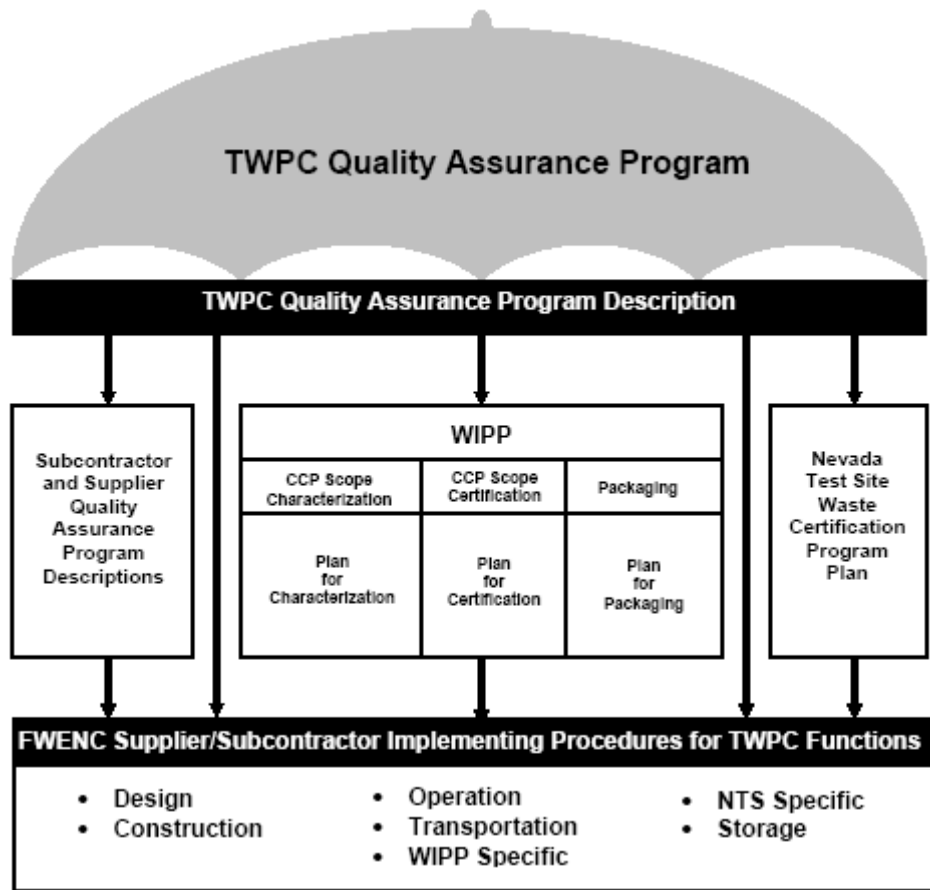


Figure 2.0-2
TRU Waste Processing Center
Quality Assurance Program Defining Documents



Quality Assurance Program Description

4.1 Management

4.1.1 Program

The Executive Vice-President (EVP) and General Manager (GM), who reports to the DOE ORO Program Manager, has the overall responsibility for developing and assuring effective execution of the QAP. The TWPC organization as of this revision is depicted in Figure 4.1. Sufficient resources are provided to achieve TWPC contracted objectives. This includes sufficient resources to develop, implement, and maintain the QAP described in this QAPD.

To emphasize the TWPC's commitment to a formal QAP, the GM annually issues and/or posts a quality assurance policy statement to TWPC personnel and subcontractors. This quality assurance policy statement is consistent with the statement at the beginning of this QAPD.

The delegation of authority to carry out various QAP activities is defined in the following sections. This does not preclude the further delegation of authority as needed to accomplish QAP objectives.

4.1.1.1 Line Organization Roles and Responsibilities

To execute assigned responsibility, the GM has delegated the execution of the QAP to line managers as depicted in Figure 4.1. The line management of the TWPC organization is responsible for the attainment of quality and assuring the quality of activities conducted as a part of the TWPC scope of work. In carrying out these responsibilities, line management obtains assistance and expertise from the Environmental Programs and Permitting (EPP) and Safety, Health and Quality (SH&Q) support organizations. The EPP and SH&Q organizations provide services to line management in the form of reviews, assessments, surveys, and technical support, as needed. In addition, the Performance Assurance organization provides compliance assessment, reporting and measurement support to line organizations.

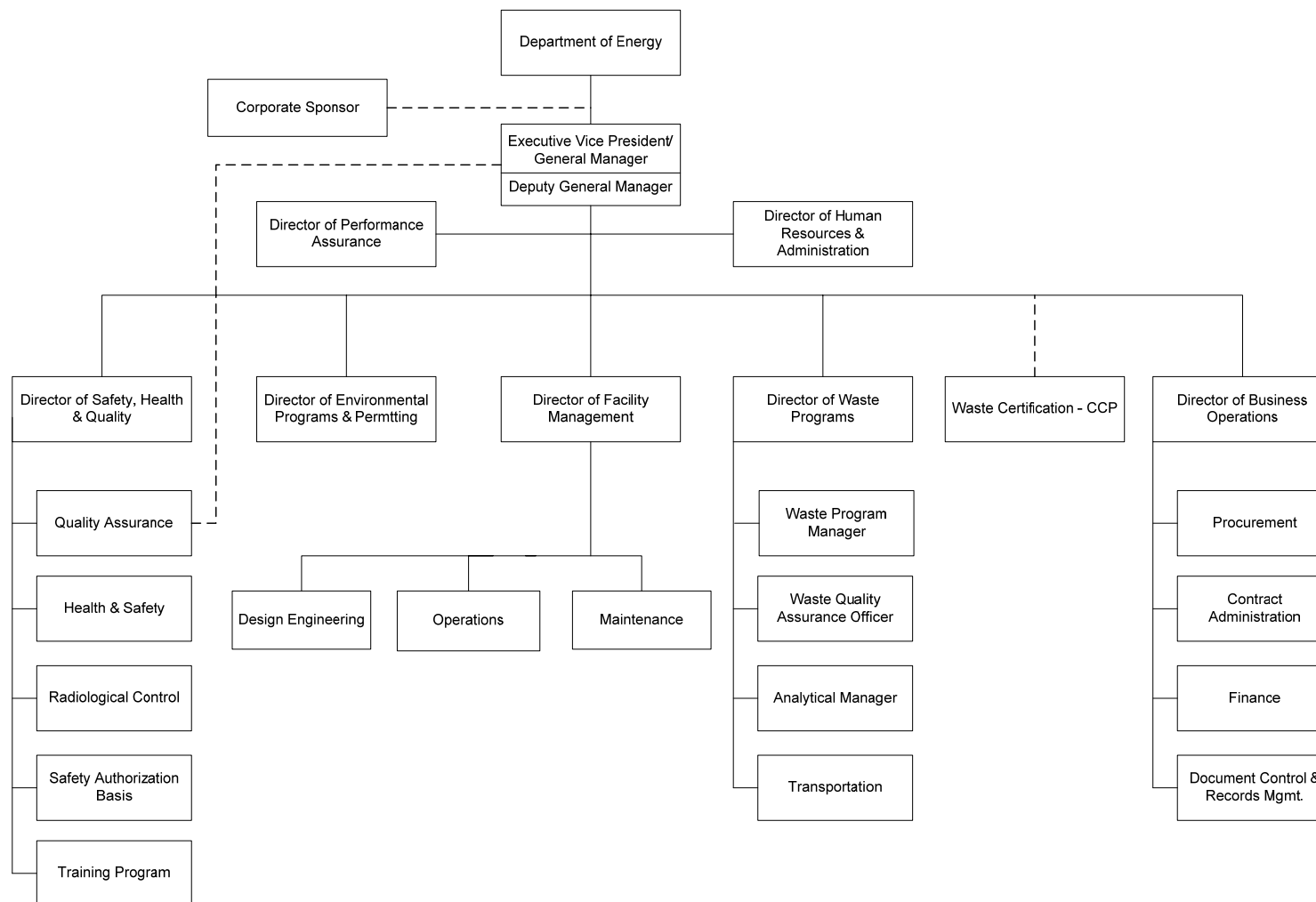
4.1.1.2 Quality Assurance Organization Roles and Responsibilities

The GM has assigned the Quality Assurance Manager (QAM) as the individual to assist in ensuring the overall implementation, adequacy, and effectiveness of the QAP. The QAM is at the same level as other managers having quality-affecting line responsibilities. The QAM reports administratively to the SH&Q Director and functionally to the GM. This direct line to the GM ensures the independence of the Quality Assurance function from line management. This includes the authority and responsibility to verify the adequacy and implementation effectiveness of major subcontractor and supplier QAPs. The SH&Q Director and the EPP Director are responsible for assuring that the TWPC quality assurance, health and safety, and environmental compliance programs are implemented in accordance with regulatory and TWPC requirements and integrated for effectiveness. The QAM is sufficiently independent from cost and schedule considerations.



Quality Assurance Program Description

Figure 4.1
TWPC Organization



**Quality Assurance Program Description**

Since the SH&Q Director has duties unrelated to quality assurance, the SH&Q Director has appointed a QAM who is able to devote full attention to quality assurance matters. To provide additional assurances of unimpeded feedback of quality-related and assurance information, an administrative channel through which the QAM can report quality or performance problems directly to the GM has been established.

The basic functions and responsibilities of the QAM are listed in Section 4.1.1.6. The following paragraphs expand on these responsibilities and functions.

In addition to performing QAP management functions, the QAM performs independent and management assessments for the TWPC organization and the GM. The QAM also provides the GM with assessments of the adequacy and effectiveness of the QAP through the assessment and surveillance process. This QAP feedback information is then used to contribute towards QAP improvement activities.

To direct the QAP, the QAM also performs the following functions:

- Planning the overall QAP
- Developing and maintaining this QAPD
- Developing and recommending for approval QAP-implementing policies, procedures, and instructions
- Reviewing QAPDs, policies, procedures, and instructions prepared by major subcontractors and suppliers and recommending acceptance

An independent assessment of overall QAP adequacy and effectiveness is performed annually on behalf of the GM.

4.1.1.3 Individual Personnel Roles and Responsibilities

TWPC personnel are empowered through their managers to be responsible for the quality of their own work. TWPC management empowers individual employees by:

- Promoting open channels of communications between management and staff
- Providing employees with the expectation to complete training and maintain qualifications to successfully accomplish their work
- Providing employees with the level of authority needed for the successful accomplishment of their work
- Providing systems and controls for employees to use to successfully accomplish their work



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4.1.1.4 Subcontractor and Supplier Roles and Responsibilities

FWENC is the prime contractor for the TWPC with full authority, responsibility and accountability for TWPC activities. FWENC has contracted with EnergyX TN who serves as the Managing Contractor. They provide all of the functions of the prime contractor for the TWPC. The FWENC team consists of several subcontractors and suppliers. Major subcontractors and suppliers who have responsibility and liability for their assigned scopes of work are typically required by contracts to implement TWPC contracted requirements under their own QAPs. Appropriate requirements are transferred and awareness of the enforceable aspects of 10 CFR 830.122 and DOE Order 414.1C are communicated to major subcontractors and suppliers as described in Section 4.1.1.5. The remaining subcontractors perform work activities that are assured, as required, in accordance with the TWPC QAP using approved procedures.

4.1.1.5 Transferring Requirements to Major Subcontractors and Suppliers

QAP activities required of major subcontractors and suppliers are specified in subcontracts or appropriate task orders under contracts. These contracts/task orders include the documents containing the requirements listed in Section 4.2.3. Requirements may be specified directly in the contract or task order scope of work statements, or the appropriate requirement document may be referenced as applicable.

4.1.1.6 Functions and Responsibilities of Key TWPC Personnel

Position/Name	Responsibilities	Authority	Reports To
Executive Vice-President & General Manager (GM)	<ul style="list-style-type: none">Provides direction for safety and health, technical resolution, process operations, permitting and interfaces, financial management, administration, scheduling, subcontracting, and resource management.Ensures TWPC contractual, environmental, SH&Q, and regulatory performanceImplements and manages the Safety Management SystemEnsures DOE satisfaction with work performed and compliance with contract requirementsCoordinates communication between DOE and Foster Wheeler EnvironmentalProvides team resources	<ul style="list-style-type: none">Authorizes stop work authority to TWPC personnelAuthority to direct all activities at the TWPCHiring and managing staff, reorganizing TWPC structures, and evaluating and implementing policy decisionsHas signature authority for contract modificationsCommits resourcesEnforces TWPC requirementsApproves TWPC policies, plans and proceduresApproves submittals to DOE	Corporate Senior Management



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Position/Name	Responsibilities	Authority	Reports To
Deputy General Manager (DGM) and Manager of Special Projects	<ul style="list-style-type: none">Ensures operations are planned to be compliant with the DOE approved Safety Authorization BasisProvides leadership and direction to TWPC personnelImplements and manages the Safety Management SystemEnsures overall safe operations and adherence within the safety basisProvides technical & operational guidanceEnsures compliance with administrative and reporting requirementsParticipates in environmental, SH&Q assessments and major incident investigationsIssues TWPC documents, as appropriate	<ul style="list-style-type: none">Authorizes work restart following a work suspensionApproves plans and procedures, as appropriateApproves purchase requisitions for services and equipmentApproves invoices for payment	GM
Performance Assurance Director	<ul style="list-style-type: none">Assess, analyze and report TWPC's compliance to contractual and regulatory requirementsIntegrates TWPC compliance with DOE Order 226.1Works with the TWPC management team to identify performance indicatorsAssesses and measures performance against performance indicatorsDocuments and analyzes performance trends and resultsIdentifies improvement objectivesEnsures TWPC readiness for new and modified activities	<ul style="list-style-type: none">Is the primary interface for response to DOE Performance Assurance AssessmentsSets Performance Assurance measurement criteria and performs assessmentsSummarizes and reports performance assurance results against predetermined goals	GM/DGM



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Position/Name	Responsibilities	Authority	Reports To
Director of Human Resources and Administration (DHRA)	<ul style="list-style-type: none">• Manages the human resources function• Develops personnel policies• Manages the employee benefits program• Hires and terminates employment• Verification of education and experience for employees• Manages the substance abuse and employee concerns programs	<ul style="list-style-type: none">• Authority to hire and terminate TWPC employees• Approves position descriptions• Evaluates and approves employee benefits administration and delivery of services• Reviews employee performance evaluations and complaints for compliance with laws and regulations	GM/DGM
Safety, Health and Quality (SH&Q) Director	<ul style="list-style-type: none">• Provides oversight of SH&Q programs• Assigns SH&Q personnel/equipment to support TWPC activities• Participates in assessments and major incident investigations• Verifies implementation of corrective actions	<ul style="list-style-type: none">• Authorizes work restart following a work suspension• Assesses TWPC performance for compliance with contractual requirements• Monitors corrective actions for compliance and nonconformance	GM/DGM



Quality Assurance Program Description

Position/Name	Responsibilities	Authority	Reports To
Quality Assurance Manager (QAM)	<ul style="list-style-type: none">• Ensures implementation and compliance with requirements of 10 CFR 830.120 and DOE Order 414.1C• Ensures compliance with TWPC procedures and other guidance documents• Develops and maintains TWPC QAPD, and quality assurance/quality control procedures• Reviews quality control and sampling plans• Supervises quality assurance/quality control staff• Develops and implements quality control training programs• Participates in assessments and major incident investigations• Verifies implementation of corrective actions• TWPC point of contact for DOE environmental, SH&Q Suspect Counterfeit Items (S/CI) Notices.	<ul style="list-style-type: none">• Performs quality assessments and audits• Initiates QA holds on equipment, services, or work in progress• Reviews and approves corrective actions to resolve quality nonconformance• Reports directly to the GM and administratively to the SH&Q Director on matters regarding quality• Approves quality reports and submittals	GM/SH&Q Director
Health and Safety Manager/Officer (HSM/HSO)	<ul style="list-style-type: none">• Ensures compliance with Occupational Safety and Health Administration (OSHA), and DOE health and safety programs• Prepares TWPC health and safety plans• Develops and implements industrial health and safety training• Maintains OSHA logs, reports and records• Maintains industrial health and safety monitoring equipment• Implements health and safety program policies and procedures• Performs assessment related to industrial health and safety requirements• Recommends industrial health and safety supplies and equipment	<ul style="list-style-type: none">• Assesses and prescribes corrective actions for industrial health and safety compliance• Stops work for industrial health and safety noncompliance	SH&Q Director



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Position/Name	Responsibilities	Authority	Reports To
Radiological Control Manager/Officer (RCM/RCO)	<ul style="list-style-type: none">Ensures compliance with OSHA and 10 CFR 835Establishes and implements TWPC radiological protection criteriaServes as primary point of contact with DOE Radiological Control staffMaintains radiological monitoring equipmentEstablishes and implements the TWPC As Low As Reasonably Achievable (ALARA) programEnsures that worker exposure is maintained ALARASpecifies technical requirements for radiological protection supplies and equipment	<ul style="list-style-type: none">Approves radiological protection plansApproves Radiological Worker Permits (RWPs)Stops work for radiological safetyAssesses and prescribes corrective actions for radiological safetyApproves/recommends upgrade/downgrade of radiological protection controls	SH&Q Director
Safety Authorization Basis (SAB) Manager	<ul style="list-style-type: none">Provides oversight of the development and update of the TWPC Documented Safety Analysis/Technical Safety Requirements (DSA/TSRs)Prepares DSA/TSRs updates for submittal to DOE for approvalEnsures the Unreviewed Safety Question (USQ) process is implemented and compliant with requirements	<ul style="list-style-type: none">Evaluates proposed changes to the DSA/TSRs and approve or reject as appropriate	SH&Q Director
Training Program Manager (TPM)	<ul style="list-style-type: none">Manages TWPC training program design, developmentImplements the TWPC training programTimely scheduling and delivery of relevant classroom training, orientation, performance based training, and visitor trainingManagement of TWPC personnel and visitor training statusDevelops and approves lesson plans	<ul style="list-style-type: none">Authorizes training program design and implementationReviews training needs assessmentsEvaluates training delivery performance and adequacyReviews program documents when issued and revised to identify additional training or retraining requirements	SH&Q Director



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Position/Name	Responsibilities	Authority	Reports To
Environmental Programs and Permitting (EPP) Director	<ul style="list-style-type: none">Ensures environmental programs are implemented and meet regulatory complianceProvides guidance related to environmental program complianceProvides guidance for waste characterizationAssures TWPC performance for compliance with regulatory requirementsSpecifies training/qualification requirements for TWPC personnel under permit requirements	<ul style="list-style-type: none">Reviews proposed modifications to permits and recommends approval	GM/DGM
Director of Facility Management (DFM)	<ul style="list-style-type: none">Manages safe, compliant and efficient TWPC Facility operationsIntegrates facility design modifications and upgrades, facility and equipment maintenance and OperationsManages Facility Security and Emergency Response capabilityImplements the TWPC maintenance programApprove Maintenance Implementation Plan (MIP)Ensures TWPC operations are performed within authorized safety basis	<ul style="list-style-type: none">Authorizes waste receipt of waste containersAuthorizes processing of waste within the TWPC complexApproves facility repairs, modifications and upgrades	GM/DGM
Design Engineering Manager (DEM)	<ul style="list-style-type: none">Ensures the design basis is consistent with the Safety Basis as approved in the DSA/TSRsEnsures final design meets local, state, and federal codes and regulationsMaintains a configuration management processSupports implementation of the MIPDevelops technical specifications	<ul style="list-style-type: none">Approves specific design documentsRecommends for approval changes to the physical plantApproves requisitions for equipment and services	DFM



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Position/Name	Responsibilities	Authority	Reports To
Operations Manager (OM)	<ul style="list-style-type: none">Ensures operations are conducted compliant with the Safety BasisEnsures daily activities are conducted in accordance with the principles of Conduct of OperationsResponsibility for daily operations in Process/Operations Area (including equipment installation and start-up)Ensures operations activities comply with environmental, SH&Q activitiesConducts reviews of process operations data and reportsRecommends modifications to process operations as conditions changeSchedules process operations personnel, equipment, and material resources	<ul style="list-style-type: none">Recommends approval of process/operation plans and proceduresAuthorizes work on safety significant systems, structures, and components	DFM
Maintenance Manager (MM)	<ul style="list-style-type: none">Plans and performs TWPC preventive and corrective maintenance activitiesMaintains TWPC buildings and grounds to DOE standardsDevelop MIP and coordinate implementationCoordinates facility upgrades at the TWPC utilizing maintenance personnelEnsures maintenance activities comply with environmental, SH&Q requirementsManages subcontractor maintenance personnel to support the facility	<ul style="list-style-type: none">Authorize implementation of approved work orders for TWPD maintenance and facility upgrades	DFM
Director of Waste Programs (DWP)	<ul style="list-style-type: none">Point of contact with the DOE Central Characterization Project (CCP), which is the DOE designated entity for all Transuranic (TRU) Waste characterization and certification for disposal at the Waste Isolation Pilot Plant (WIPP)Overall responsibility for TWPC waste program design, maintenance and implementationEnsures performance of waste certification and analytical laboratory activitiesEnsures processed waste meets all repository requirements	<ul style="list-style-type: none">Authority to approve waste program documentationApproves/resolves waste program deviationsEvaluates waste processing performance against contractual obligations and formulates actions to achieve waste production targets	GM/DGM



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Position/Name	Responsibilities	Authority	Reports To
Waste Programs Manager (WPM)	<ul style="list-style-type: none">Provides the day-to-day management of waste-related activitiesDevelops and maintains waste-related program, and proceduresConducts assessments of waste program(s) effectivenessEnsures the training and qualification of Waste Programs personnelMonitors waste characterization, analysis, certification, and transportation activitiesOversees onsite waste-related work conducted by sub-contractors	<ul style="list-style-type: none">Oversight of onsite waste-related workSpecifies training and qualification requirements for waste programs personnel	DWP
Waste Quality Assurance Officer (WQAO)	<ul style="list-style-type: none">Responsible for TWPC Quality Assurance and Quality Control activities related to waste receipt, acceptance, storage, movement, processing, and packagingPerforms receipt inspections of waste related procured itemsPerforms supplier surveys, assessments, audits, and surveillances of subcontractor and of TWPC waste operations and support activitiesValidates waste related nonconformance reports and corrective actionsPerforms analysis of adverse trends related to waste issues	<ul style="list-style-type: none">Reviewing waste-related documents, procedures and preparing recordsApproving WNCRs and WCARs for waste-related non-conformances and evaluating waste related corrective action effectiveness	DPM
Analytical Manager (AM)	<ul style="list-style-type: none">reviews and analyzes waste characterization data, waste processing data and comparing these data against the waste acceptance requirements of the disposal facility	<ul style="list-style-type: none">Review and analyze waste data for accuracy and compliance with DOE, DOT and Disposal Facility WACEvaluate waste data generated during processing for adequacy, accuracy, and acceptabilityReviews and approves laboratory waste characterization and supporting documentation	WPM



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Position/Name	Responsibilities	Authority	Reports To
Transportation Manager (TM)	<ul style="list-style-type: none">Reviews inbound shipments for compliance to transportation regulationsCoordinates the acceptable packaging and shipping of processed LLW and MLLW to the designated licensed disposal facility	<ul style="list-style-type: none">Approve container selection and packaging of waste into authorized containersApprove shipping manifest for out-bound shipmentsApprove selection of transportation company for compliance with DOT regulationsReview TWPC transportation documentation, plans, procedures, reports, etc.	DWP
Central Characterization Project (CCP)	<ul style="list-style-type: none">Overall responsibility for WIPP characterization and certification of all TRU waste being processed at the TWPC. Activities (as applicable) such as nondestructive examination, nondestructive assay, head-space gas sampling and analysis, and summa sampling and analysis are all within the CCP scope of work as defined in their contract with DOECoordinates and performs waste characterization and certification activities. (The TWPC will perform other aspects of WIPP bound waste processing except shipping which will be performed by DOE.)	<ul style="list-style-type: none">Approves Acceptable Knowledge compilation, revisions, reconciliations, updates, and reportingApproves NDA, NDE and HSGS testing and data reporting resultsEvaluates existing waste for processing and shipmentIssues Waste Certification and Transportation CertificationApproves Waste Shipment to WIPP	DOE
Director of Business Operations (DBO)	<ul style="list-style-type: none">Manages business operations including contracts, procurement, finance, accounting, project controls, information technology, warehousing and material stores, document control and records managementEvaluates TWPC performance against contractual business obligationsPlans and approves IT operations at the TWPCBudgets and approves document control and records management center operationsSupports implementation of MIP	<ul style="list-style-type: none">Authorizes the TWPC budgetAuthority to enter into binding contractsApproves accounting practices and procedures	GM/DGM



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Position/Name	Responsibilities	Authority	Reports To
Procurement Manager (Proc Mgr)	<ul style="list-style-type: none">• develops and maintains of the TWPC procurement program consistent with Federal Acquisition Regulations• Manages the TWPC procurement process including procurement planning and administration, reporting and maintaining qualified suppliers	<ul style="list-style-type: none">• Authorizes procurement planning activities• Authority to issue purchase orders• Approves procurement packages• Assess procurement actions against federal acquisition regulations	DBO
Contract Administrator (CA)	<ul style="list-style-type: none">• Facilitates TWPC's contractual compliance• Reviews contract modifications and makes recommendations		DBO
Finance Manager (Fin Mgr)	<ul style="list-style-type: none">• Responsible for financial management at the TWPC• Prepares/validates budgets for the TWPC, prepares cost estimates, sets up accounts according to WBS breakdown• Monitors spend rates and prepares reports including earned value data for reporting to the DOE	<ul style="list-style-type: none">• Set-up and maintain financial accounts• Approves charge numbers	DBO
Document Control and Records Management (DCRM) Manager	<ul style="list-style-type: none">• Develops and maintains the TWPC file index and electronic and hard copy capture, maintenance and final disposition of TWPC records and documents• Implements the TWPC document control and records management programs• Develops and maintains TWPC document control and records management procedures• Staffs, manages and controls access to DCRM facilities• Facilitates identification, unique numbering, preparation, approval and controlled distribution of TWPC documents• Develops and maintains electronic records archival process and system• Maintains control of records facilities and protects records• Distribute documents to external users	<ul style="list-style-type: none">• Authorize controlled distribution of approved TWPC plans, procedures, etc.• Authority to dispose of records	DBO

**Quality Assurance Program Description****4.1.1.7 Interface Control**

The free and continuous flow of communications both horizontally and vertically within the TWPC organization and external to the TWPC is essential to the execution of the QAP. To promote the flow of communications and to assure positive attention to quality problems the following key interfaces have been identified between DOE ORO and the TWPC and between the TWPC and major subcontractors/suppliers:

- Communications by Senior Management

These communications deal with such matters as major changes in the scope of the QAP. Communications are addressed to the responsible senior management official with copies to the major TWPC participants cognizant of the subject.

- Communications by Quality Assurance Management

These communications provide a direct formal and informal exchange of information between the QAM and other QAMs of organizations that have a direct interface with the TWPC. Formal communications are concurred with and approved by the SH&Q Director. Copies of such communications are distributed to other major TWPC participants cognizant of the subject, as appropriate.

- Communications by Individuals

These communications are encouraged to identify and evaluate quality problems and to initiate, recommend, or provide solutions. Communications may be formal or informal, the choice depends on the significance of the subject and the judgment of the individuals involved.

Individuals responsible for these interfaces and methods of communication are described in TWPC documents. In addition, the TWPC has developed an issues and commitment control system to control the exchange of important interface information.



4.1.1.8 Graded Approach

The QAP is applied to TWPC work activities. The scope, depth, and rigor of this application are determined using a grading process. The basis for this approach lies in the fact that the facility is a Category 2 Non-Reactor Nuclear Facility and the approach requires the implementation of appropriate and commensurate controls for identified hazards and risks. Three basic levels of controls are established, with the flexibility to further refine the applicability of the controls or degree of assurance on a case-by-case basis during the work planning or procurement process. Systems and parts of systems, activities, functions, and services are classified as Category A, B, or C. The selection of Category A, B, or C is based on the potential hazards and risks to public health and safety and/or worker health and safety in the event of failure or malfunction. Criteria identified for this categorization include, for example:

- The safety significance of structures, systems, or components
- The relative importance to safety and safeguards
- The magnitude of any hazard involved
- The life cycle stage of the TWPC activity
- The likelihood of a failure, or series of failures, necessary to create a hazard
- Importance to waste product acceptance
- Other relevant factors as may be determined from time to time

The portion of work classified as Category A receives the highest level of effort in implementing 10 CFR 830 Quality Assurance requirements.

The categorization and application of specific controls is accomplished according to TWPC procedures during the work planning and for the procurement process. Procedures ensure the communication, documentation, and maintenance of the assignment, as required.

4.1.2 Personnel Training and Qualification

The qualification requirements of TWPC personnel are evaluated against job functions and met prior to performing activities that affect quality. Key members of the TWPC management team had their qualifications evaluated by DOE and were determined to be qualified.

These key personnel are provided with TWPC-specific training and orientation as necessary to meet applicable training requirements. Other TWPC personnel who perform activities affect quality are subject to the qualification process described below.

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The TWPC Management determines the entry-level education, experience, training, and qualification requirements for positions that perform activities that affect quality. These qualification requirements take into consideration training required by laws, regulations, and client requirements. Based on qualification requirements, the TWPC Manager assigns training elements to personnel in the form of an individual training profile to achieve qualification. The TWPC Management then monitors the performance of personnel and adjusts the training and qualification requirements as necessary. This includes required retraining, continuing training, or personnel development activities as part an ongoing performance appraisal process.

Records of training and qualification are documented and maintained in the TWPC record files. Line managers ensure activities affecting quality are performed and documented as required.

The TWPC specifies training and qualification requirements to subcontractors who perform activities affecting quality and assigns the responsibility to the subcontractor to ensure completion of these requirements. These activities are performed according to TWPC requirements specified in procurement documents.

The TWPC controls this assigned work through the subcontractor assessment/verification process, which includes review, surveillance, and audit of the major subcontractor's personnel training and qualification activities.

4.1.3 Quality Improvement

To promote prevention, detection and correction of quality problems and improvement in TWPC work activities, the following methods are used:

- Continuing personnel development activities
- Implementing the principles and functions of the Safety Management System and process
- Implementing the assessment/verification processes of DOE Order 414.1C, 10 CFR 830.122, and DOE Order 226.1

4.1.3.1 Continuing Personnel Development Activities

The TWPC provides continuing training to personnel to maintain and improve proficiency. Continuing training is provided using the same delivery methods as initial training and through development activities identified through the performance appraisal process.

4.1.3.2 Implementing the TWPC Assessment/Verification Process

The assessment/verification process is a five-step process that includes:

- Planning assessments/verifications

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- Conducting assessments/verifications
- Analyzing QAP feedback data and correcting deviations
- Reporting the results of assessment/verification activities to responsible management
- Improving work processes and products

This cyclic process is depicted in Figure 4.1.3-1. The following Sections provide additional details on how the TWPC accomplishes this five-step process.

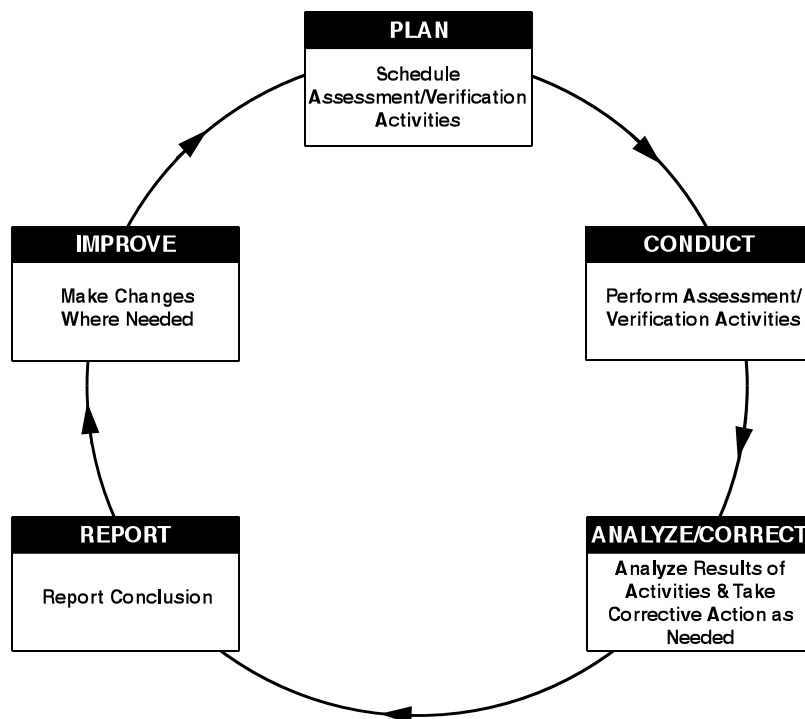


Figure 4.1.3-1
TRU Waste Processing Center Assessment/Verification Process

Step 1. Plan Assessments/Verifications – Assessment/verification plans are the key to the entire assessment/verification process. Based on the TWPC contract schedule, previous QAP feedback data and extent of QAP application, line management and the QAM use the planning process to determine the following:

- What scope of work to evaluate
- When and how often to perform evaluations (assessments and verifications)
- What type of evaluation activity to perform
- Who will perform the evaluation activity



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Additional details on planning assessments/verifications are contained in Sections 4.3.1 and 4.3.2.

Step 2. Conduct Assessments/Verifications – This step consists of line organizations and quality assurance support personnel conducting those assessments/verifications planned in step one, as well as any necessary unplanned assessments/verifications. These assessment/verification activities consist of the following types of activities:

- Audits
- Appraisals
- Surveillances
- Inspections
- Reviews
- Assessments

Additional detail on conducting assessments/verifications is contained in Sections 4.3.1 and 4.3.2.

Step 3. Analyze QAP Feedback Data and Take Corrective Action (as needed) – This step consists of line organizations and the QAM analyzing QAP feedback data from the following kinds of sources:

- DOE ORO assessments
 - DOE headquarters assessments
 - Assessment/verification activities (internal and external)
 - TWPC reportable occurrences
 - TWPC nonconformance/corrective action reports
 - TWPC trend analysis reports
 - Subcontractor-submitted documents
 - Subcontractor nonconformance/corrective action reports
 - Subcontractor reportable occurrences
 - Subcontractor trend analysis reports
 - Regulatory agency reports
-



TWPC internal and external assessment/verification activities identify the need for controlling nonconformances and taking corrective action. Procedures detail the mechanisms for identifying, documenting, evaluating, tracking, following up, and closing out deviations. For deviations involving a nonconforming item, procedures also provide a mechanism for segregating or otherwise controlling the suspected nonconforming item to prevent inadvertent use. Deviation means that there is a departure of one or more characteristics of an item or an activity from a requirement, including any departures that are associated with PAAA Rule commitments.

Deviations identified during internal and external overview activities are documented. Each deviation is evaluated by responsible line management to determine if the deviation represents a condition adverse to quality or a significant condition adverse to quality. Deviations that are adverse to quality are tracked to closure and evaluated by the PAAA Coordinator for initial categorization as a potential PAAA noncompliance, if warranted. Deviations that are determined to not be conditions adverse to quality are dispositioned by responsible line management. Deviations that are determined to be significant conditions adverse to quality, including any potential PAAA noncompliances, are preliminarily dispositioned and followed by additional analysis of causes and contributions. Significant conditions adverse to quality that are also determined to be potential PAAA noncompliances are reviewed by the Senior Review Board as described in implementing procedures, and when warranted by the level of significance, are reported to DOE for inclusion in their Noncompliance Tracking System. These conditions are addressed and processed according to the TWPC tracking system through closure.

Additional evaluations are performed to determine if similar deviations exist that have previously gone undetected and uncorrected. If such conditions are discovered, they are documented and dispositioned. Actions are initiated to eliminate the condition that initially allowed the deviation and to prevent such deviations from recurring. Trend analysis may also identify quality problems, which are reviewed to determine if the problem is a significant condition adverse to quality. The responsible TWPC organizations or subcontractors are required to provide remedial action, as well as actions to preclude recurrence.

This QAP feedback data is analyzed by responsible line management, and necessary corrective action or improvements are made. Additionally, information from internal and external audit reports, surveillance reports, surveys, customer reports, and employee allegations are used in analyzing trends. TWPC procedures require trend reporting, evaluation, and appropriate corrective action.

Step 4. Reporting the Results of Assessment/Verification Activities to Responsible Management – This step involves reporting the conclusions drawn during the analysis process above, as well as conclusions drawn during individual assessments/verifications. Line organizations and the QAM report conclusions drawn from individual assessments/verifications on an ongoing basis to TWPC management.

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Conclusions drawn from the annual independent assessment of the overall QAP are reported to the GM. The GM in turn reports on Quality Program implementation to the DOE ORO Program Manager as a part of normal TWPC reporting.

Step 5. Improve Work Processes and Products – This final step involves line organizations and the QAM in monitoring QAP feedback data for adverse quality trends and problems. When an adverse quality trend or problem is identified, line managers initiate changes to improve process or product quality and to prevent future problems.

The TWPC assigns the responsibility for executing quality improvement activities related to assigned scopes of work to major subcontractors and suppliers to which the particular scope of work is assigned. These activities are performed according to requirements identified in procurement documents.

The TWPC controls this assigned work through the subcontractor assessment and verification process, which includes review, surveillance, and/or audit of the major subcontractor's quality improvement activities.

4.1.4 Documents and Records

4.1.4.1 Documents

The TWPC controls quality-affecting documents received from external sources which impose requirements on activities and internal documents including the TWPC QAPD, procedures, instructions, etc.

The TWPC document control system consists of three components:

- Control of TWPC-issued documents
- Receipt and control of externally issued documents
- Control of data to support waste certification

Preparing, approving, revising, and issuing TWPC documents are described in implementing procedures. Typical TWPC documents subject to control are as follows:

- Policies
- Plans
- Procedures
- Baseline and configuration defining documents (e.g., drawings, specifications, sampling plans, schedules, authorization basis etc.)
- Procurement documents



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- Requirements implementation and/or traceability matrices
- Work planning documents
- Safety Management System Description
- Waste characterization data
- Waste certification documentation
- License and permit applications

The procedures defining the control process for these documents specify reviews and approval required prior to issuance.

The TWPC receives controlled quality-related documents issued by external organizations. These documents include but are not limited to the following:

- DOE Directives
- Subcontractor (including supplier) documents
- Federal, state or regulatory documents (licenses and permits)
- Waste acceptance criteria, including lower-tier documents

TWPC documents are controlled to ensure that they are available where and when needed, the latest revision is identified and maintained, and superseded material is indicated as such, removed or destroyed (using Table of Contents, Controlled Lists of Document Holders, and Records of Receipt).

The TWPC controls action items by using a commitment control system. Items that are entered and tracked to completion include:

- External direction documents requiring TWPC action, such as DOE, state, or regulatory agency directives
- Documents requesting subcontractor actions and replies
- TWPC internal action items

The TWPC assigns the responsibility for executing document control activities related to assigned scopes of work to major subcontractors and suppliers in accordance with requirements included in procurement documents.

The TWPC controls this assigned work through the subcontractor assessment/verification process, which includes review, surveillance, audit, and inspection of major subcontractor document control activities.



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4.1.4.2 Records

The TWPC implements an integrated records management system to collect, manage, and store quality records as work progresses. This includes collecting major subcontractor quality records as work progresses.

Procedures specify the quality records that result from performing quality-related activities defined in the procedures. Responsibilities for preparing records are specified in the procedures. Document and record retention is also proceduralized.

The TWPC manages these quality-related records as a consequence of:

- Licensing and permitting
- Designing, procuring and constructing the waste treatment facility and associated equipment
- Receiving, characterization, treatment, certification, packaging, transportation, and disposing of waste
- Implementing the QAP
- Implementing environmental, safety, and health requirements and initiatives

Technical requirements for the work (laws, regulations, standards, directives, and specifications) identify the records to be prepared and maintained. The TWPC records management system collects, prepares, and maintains the required records.

The TWPC performs its records management activities in accordance with procedures that implement requirements. The procedures provide guidelines, responsibilities, and requirements for record preparation, record review, validation/approval, interim control of records, transmittal for handling, storage, and retrieval.

The QAM assures that indexes (e.g., record retention times and storage locations) for and maintenance of records is accomplished within the TWPC records management system.

The TWPC assigns the remaining responsibility for executing quality records activities related to assigned scopes of work to major subcontractors and suppliers in accordance with requirements included in procurement documents. This includes requirements for transfer of quality records to the TWPC as work progresses, rather than just at the end of the work scope.

The TWPC controls this assigned work through the subcontractor assessment/verification process, which includes review, surveillance, audit and inspection of major subcontractor records preparation and records management activities.



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4.2 Performance

4.2.1 Work Processes

4.2.1.1 Work

A system of approved policies, plans, procedures, and guidelines, describe how TWPC manages and performs work safely and compliantly. Work is accomplished according to these procedures and guidelines. When TWPC-specific procedures are required, procedures are reviewed using a graded approach by TWPC technical, environmental, and SH&Q specialists to ensure that technical, environmental, and SH&Q requirements are correctly included prior to approval by the respective line manager responsible for implementing the procedure.

Procedures include or refer to appropriate acceptance criteria for determining that prescribed activities are accomplished satisfactorily. Procedures also include the following, as appropriate to the particular procedure type:

- Procedure purpose
- Procedure scope
- Responsible organization for procedure maintenance
- Organizational and/or individual responsibilities
- Technical, regulatory, quality assurance, and other requirements
- Sequential description of the work to be performed
- Safety prerequisites, limits, precautions, process parameters, and environmental conditions
- Special qualification and training requirements
- Verification points and hold points
- Methods for demonstrating that the work was performed as required, such as a sign-off block
- Identification, classification, and proper handling of the document to be prepared as quality records
- Definitions of terms and acronyms

Other documents that the TWPC uses, such as subcontractor or supplier manuals, drawings, and specifications, are prepared and maintained by the originating organizations in accordance with their respective QAPs.

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The TWPC assigns the remaining responsibility for executing work control activities related to assigned scopes of work to these major subcontractors and suppliers. These activities are performed according to requirements included in procurement documents.

The TWPC controls this assigned work through the subcontractor assessment/verification process, which includes review, surveillance, audit, and inspection of major subcontractor preparation, use, and maintenance of instructions, procedures, and drawings.

4.2.1.2 Identification and Control of Items

The TWPC implements an identification and control practice to support work requiring traceability related to quality-related items (including samples and treated waste, consumable, service or software) determined to be of special importance, where traceability is required.

TWPC's line organizations are required to determine specific identification and control requirements during planning according to requirements. Their practice assures the following:

- That identification is maintained either on the item, attached to the item, or on records and containers traceable to the item as required
- The item can be traced to the appropriate documentation such as drawings, specifications, lot numbers, purchase orders, manufacturing and inspection documents, deviation reports, and physical and chemical mill test reports
- The method and location of the identification does not affect the function or quality of the item being identified
- The correct identification of items accomplished and verified prior to the release for fabrication, assembly, shipping, and installation

These practices are designed to preclude the use of incorrect or defective items important to waste acceptance, the environment or SH&Q activities.

The TWPC assigns the remaining responsibility for identification and control of items related to assigned scopes of work to major subcontractors and suppliers in accordance with requirements included in procurement documents.

The TWPC controls this assigned work through the subcontractor assessment/verification process that includes review, surveillance, audit, and inspection of major subcontractor identification and control activities.

If the TWPC chooses to perform inspections or tests for acceptance purposes, and programmatic controls require the identification of correct and acceptable items, the TWPC requires the responsible major subcontractor or supplier to identify the items in accordance with the subcontractor's or supplier's procedures.



4.2.1.3 Handling, Storing, and Shipping

The TWPC implements practices for handling, storage, and shipment of items in support of waste facility operations, maintenance and modification, environmental, and SH&Q activities. TWPC organizations, with the procurement organization, are required by procedure to determine specific handling, storing, and shipping requirements during initial planning stages according to requirements. These practices include the following:

- Special handling, preservation, storage, cleaning, packaging, and shipping requirements are specified and accomplished by suitably qualified individuals in accordance with predetermined work and inspection instructions.
- Procedures are prepared in accordance with design and procurement specification requirements to establish and describe controls for the cleaning, handling, storage, packaging, shipping, and preservation of items to preclude damage, loss, deterioration by environmental conditions such as temperature or humidity, or to protect the environment and the safety and health of employees and the general public.

The TWPC assigns the remaining responsibility for executing handling, storage, and shipping activities related to assigned scopes of work to major subcontractors and suppliers. These activities are performed according to requirements included in procurement documents.

The TWPC controls this assigned work through the subcontractor assessment/verification process, which includes review, surveillance, audit and inspection of major subcontractor handling, storage, and shipping activities.

Subcontractors must inspect government-furnished equipment for damage. The TWPC may witness these inspections as a surveillance activity. Discrepancies noted by the subcontractor are reported through the DOE ORO Program Manager.

4.2.1.4 Calibration and Maintenance of Monitoring and Data Collection Equipment

The TWPC's program for calibrating and maintaining monitoring and data collection equipment is described in Section 4.2.4.

The TWPC assigns the responsibility for executing calibration and maintenance of monitoring and data collection equipment activities on assigned scopes of work to major subcontractors. These activities are performed according to requirements included in procurement documents.

The TWPC controls this assigned work through the subcontractor assessment/verification process, which includes review, surveillance, and audit of the major subcontractor's calibration and maintenance of monitoring and data collection equipment.

4.2.2 Design

The TWPC includes the following design control practices in their QAP:

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- 4.2.2.1 The scope of the design control program includes design activities associated with the preparation and review of design documents, including the correct translation of applicable requirements and design bases into design, procurement, and procedural documents.
- 4.2.2.2 Organizational responsibilities are described in procedures for preparing, reviewing, approving, and verifying design documents such as system descriptions, design input and criteria, design drawings, design analyses, computer programs, specifications, and procedures.
- 4.2.2.3 Errors and deficiencies in approved design documents that could adversely affect structures, systems, and components important to waste acceptance objectives or nuclear safety [as defined in the safety analysis reports] are documented. These approved design documents include design methods (such as computer codes). Action is taken to assure that errors and deficiencies are corrected in accordance with the major subcontractor's deviation and corrective action system.
- 4.2.2.4 Deviations from specified quality standards are identified and procedures ensure their control.
- 4.2.2.5 Internal and external design interface controls, procedures, and lines of communication among participating design organizations and across technical disciplines are established. Controls for the review, approval, release, distribution, and revision of documents involving design interfaces are clearly defined. These controls assure that items are compatible geometrically, functionally, and with processes and environment.
- 4.2.2.6 Procedures require a documented check to verify the dimensional accuracy and completeness of design drawings and specifications.
- 4.2.2.7 Guidelines or criteria are established and described for determining the method of design verification (design review, peer review, alternate calculations, or qualification test).
- 4.2.2.8 Procedures are established and described for design verification activities which assure the following:
- The verifier is qualified and is not directly responsible for the design.
 - Design verification is completed prior to release for procurement, manufacturing, construction, processing, or to another organization for use in other design activities. For cases in which this timing cannot be met, the design verification may be deferred if the justification for this action is documented and the unverified portion of the design output document and (based on the unverified data) are appropriately identified and controlled. Design changes will not proceed without verification past the point at which the installation would become irreversible (i.e., require extensive demolition and rework). The design verification must be complete prior to relying upon the item to perform its function.
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- Procedural control is established for design documents that reflect the commitments of the Documented Safety Analysis to keep the design documents consistent. This control differentiates between documents that receive formal design verification by interdisciplinary or multi-organizational teams and those that can be reviewed by a single individual (a signature and date is acceptable documentation for personnel certification). Design documents subject to procedural control include, but are not limited to, specifications, calculations, computer programs, system descriptions, the Documented Safety Analysis and unreviewed safety questions when used as a design document, and drawings including flow diagrams, piping and instrument diagrams, control logic diagrams, electrical single line diagrams, important structural systems, site arrangements, and equipment locations.
- The responsibilities of the verifier, the areas and features to be verified, the pertinent considerations to be verified, and the extent of documentation to be maintained are identified in procedures.

4.2.2.9 The following provisions are included if the verification method is only by test:

- Procedures provide criteria that specify when verification should be by test.
- Testing of prototypes, components, or features is performed as early as possible prior to installation of equipment, or prior to the point when the installation would become irreversible.
- Verification by test is performed under conditions that simulate the most adverse conditions applicable to the item as determined by analysis.

4.2.2.10 Procedures are established to assure that verified computer codes are certified for use and that their use is properly specified, when needed for use in performing safety related design activities or operational activities.

4.2.2.11 Design and specification changes, including field changes, are subject to the same design controls that were applicable to the original design.

4.2.2.12 Procedures are established to assure documentation of a design or technical review that identifies, as a minimum, the reviewers, the area or features reviewed, the comments of the reviewers, and the resolution of the comments.

4.2.2.13 The design inputs are specified and approved on a timely basis and to the level of detail necessary to permit the design activity to be carried out in a correct manner and to provide a consistent basis for making design decisions, accomplishing design verification measures, and evaluating design changes.

4.2.2.14 The impact of design changes on procedures and training is evaluated and changes are communicated to affected groups or individuals.

The TWPC organizations review subcontractor technical documents, the QAM prepares quality assurance requirements documents, and both line and quality assurance



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organizations participate in subcontractor-initiated reviews; i.e., peer and design. These activities are prescribed in procedures for these activities. Activities performed are:

- Design Reviews – The design reviews are performed in accordance with the major subcontractor's procedures. The TWPC provides input into the review as members of the review team. Reporting, corrective actions, and records are as specified in the major subcontractor's procedures.
- Reviews of Subcontractor Furnished Technical Documents – Procedures define the actions and responsibilities required for reviewing and evaluating selected major subcontractor technical documents. They provide guidance on designating major subcontractor documents to be reviewed, general criteria for the review, and details of the process for documenting the review findings.
- Peer Reviews – The TWPC participates in major subcontractor-initiated peer reviews, which are conducted in accordance with major subcontractor procedures. The TWPC provides input into the review as a member of the review team. Reporting, corrective actions, and records are as specified in the major subcontractor's procedures.

Procedures describing and controlling these quality-related activities at a minimum address:

- Organizational responsibilities
- Review criteria
- Documents/forms, to be completed during the review, which provide or specify the quality records resulting from the reviews
- Identification and correction of deviations

The TWPC delegates the responsibility for executing design control practices on assigned scopes of work to major subcontractors. These activities are performed according to requirements included in procurement documents.

The TWPC controls this delegated design work through the subcontractor assessment/verification process, which includes review, surveillance, and audit of the major subcontractor's design and design control activities.

4.2.3 Procurement

The TWPC implements practices for control of procurement documents in accordance with requirements. This practice assures that procurement functions are accomplished in accordance with the applicable contracts, codes, standards, drawings, and specifications. This practice is carried out under written procedures that define interfaces between applicable organizations. A graded approach to procurement activities is performed consistent with Section 4.1.1.8.



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The TWPC procedures for procurement control typically contain the following provisions:

4.2.3.1 Procurement Document Preparation, Review, and Change Control

- As appropriate to the item or service being procured, requisitioners prepare procurement documents which contain the following:
 - Scope of Work
 - Technical Requirements
 - Quality Requirements
 - Special Quality Assurance Requirements (requirements for surveillance, inspection, etc., including holdpoints)
 - Right of Access
 - Documentation Requirements
 - Nonconformance Control
 - Transfer of Requirements to Lower-tier Participants
- The requisitioning organization, environmental, SH&Q, and the Purchasing Organizations perform technical, quality assurance, and adequacy reviews respectively as described in TWPC procedures.
- When completed, the Purchasing Organization provides predetermined types of purchase documents to DOE ORO for acceptance/approval.

4.2.3.2 Selection of Procurement Sources

- Purchasing evaluates and selects suppliers based upon their capability to provide services and products of acceptable quality at the best value.
 - Quality assurance and technical specialist personnel participate in the evaluation of suppliers as defined in procedures.
 - The evaluation of suppliers is based on one or more of the following:
 - The supplier is evaluated on their capability to comply with TWPC requirements (as specified in the procurement document) that are applicable to the type of item or service being procured.
 - Records are reviewed indicating performance of suppliers who have provided similar items or services of the type being procured.
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- Surveys are conducted of the supplier's facilities and quality practices to determine their capability to supply a product which meets the TWPC's design, manufacturing, and quality assurance requirements. Results of these surveys are documented and filed in Document Control.

4.2.3.3 Bid Evaluation Award

- The purchasing organization, with the assistance of technical and quality assurance personnel, evaluates the bid to determine the extent of conformance to the procurement documents. Individuals or designated organizations use written procedures to evaluate the following subjects as applicable to the type of procurement:
 - Technical consideration
 - Quality assurance requirements
 - Supplier's personnel
 - Supplier's production capability
 - Supplier's past performance
 - Alternates
 - Exceptions
- Prior to the award of the contract, the Purchasing Organization resolves unacceptable quality conditions resulting from the bid or obtains commitments for their resolution.

4.2.3.4 Purchaser's Control of Supplier's Performance

- To assure continued, sustained conformance to the purchase order requirements, applicable TWPC line organizations plan and perform (with quality assurance personnel participation) surveillance of suppliers during fabrication, inspection, testing, and shipment of items or services in accordance with written procedures. These procedures provide for the following:
 - Planning of evaluations consistent with the importance, complexity, and quantity of the product or service
 - Specification of the characteristics or processes to be witnessed, inspected or verified, and accepted; the method of surveillance and the extent of documentation required; and those responsible for implementing these procedures
 - Audits and surveillances which assure that the supplier complies with quality requirements (Surveillance is performed on those items or services where

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verification of conformance to procurement requirements cannot be determined upon receipt.)

- Special quality verification activities to provide the necessary assurance of an acceptable item or service for commercial off-the-shelf items for which specific quality assurance controls appropriate for nuclear applications cannot be imposed by the purchaser in a practical manner

4.2.3.5 Acceptance of Item or Service

Qualified line organization personnel receiving items or services review and approve supplier-furnished data according to established procedures.

Receiving personnel review supplier-generated documentation (such as certifications) for completeness, acceptability, and conformance to contract requirements and provide appropriate approval before accepting completed items and services. At receipt inspection, line personnel receiving the item or service routinely or periodically validate supplier-furnished material certifications by means of independent analysis or rechecks and document the results. The receiving organization's receipt inspection planning defines the necessary inspections and tests and provides for adjustments to inspection frequency or intensity depending upon source, quality performance history, lot size, and other factors. Receipt inspection planning is coordinated with the appropriate line organizations.

The TWPC performs the following as a part of the acceptance practice:

- Checks the item or service to ensure that it is properly identified and that it corresponds to (1) the identification on the purchase document, and (2) the receiving documentation
- Prior to installation or use, performs inspections and completes acceptance records of the items or services judged acceptable in accordance with predetermined inspection instructions
- Prior to installation or use, ensures that inspection records or certificates of conformance attesting to the acceptance of items are available from the receiving organization
- Identifies the inspection status of items accepted and released prior to forwarding them to a controlled storage area or releasing them for installation or further work
- Nonconforming items are segregated when practical, controlled, and clearly identified until proper disposition is made

Such reviews and inspections serve to ensure that suppliers continue to provide acceptable items and services.



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4.2.3.6 Corrective Action for the Procurement Process

The TWPC and suppliers establish and document methods for disposition of items and services that do not meet procurement documentation requirements. These methods provide performance information and feedback that helps to ensure that suppliers continue to provide acceptable items and services. These methods contain provisions for the following:

- Review of subcontractor capability reports – problem prevention versus problem detection initiatives
- Evaluating nonconforming items
- Supplier submittal of nonconformance disposition requests with suggested dispositions (with justification) for approval
- Disposition of supplier recommendations
- Verification of disposition implementation
- Maintenance of supplier-submitted nonconformance records

4.2.3.7 Quality Records

At a minimum, the Purchasing and Receiving Organizations prepare the following documents received from suppliers as quality records according to Section 4.1.4:

- Certifications that specifically identify (e.g., by the purchase order number) the purchased item and the specific procurement requirements (code, standards, specifications, etc.) met by the items
- Certifications that identify any procurement requirements which have not been met, together with a description of those nonconformances dispositioned "accept as is" or "repair"

The TWPC assigns the remaining responsibilities for executing procurement control activities related to assigned scopes of work to major subcontractors and suppliers. These activities are performed according to requirements included in procurement documents.

Responsible TWPC organizations control this assigned work through the subcontractor assessment/verification process, which includes review, surveillance, and audit of major subcontractor and supplier procurement control.



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4.2.4 Inspection and Acceptance Testing

4.2.4.1 Inspection

The TWPC implements an inspection practice in support of the facility, waste processing and waste certification. The TWPC's inspection practice is conducted according to procedure and identifies and verifies conformance of items (including samples and treated waste) and services with the documented specifications, instructions, procedures, and drawings for accomplishing the required activities. The practice assures the following:

- Organizational responsibilities for inspection are described and documented in procedures. Inspection personnel are independent from the individual or group performing the activity being inspected. If the individuals performing inspections are not part of the quality assurance organization, the inspection procedures, personnel qualification criteria, and independence from undue pressure (such as cost and schedule) are reviewed for acceptability by the quality assurance organization prior to initiation of the activity.
 - Procedures are developed with quality assurance organization participation to define how and when inspections are performed.
 - Inspection procedures, instructions, and checklists include the following:
 - Identification of characteristics to be inspected
 - Identification of the individuals or groups responsible for performing the inspection operations
 - Acceptance and rejection criteria
 - A description of the method of inspection, including necessary expertise
 - Specification of the necessary measuring and test equipment, including accuracy requirements
 - Identification of required procedures, drawings and specifications, including the applicable edition or revision
 - Inspection procedures or instructions are available with necessary drawings and specifications for use prior to performing inspection operations
 - Inspectors (including nondestructive test personnel) are qualified in accordance with appropriate codes, standards, and internal training programs, and their qualifications and qualification records (certifications) are kept current
 - Modifications, repairs, and replacements are inspected in accordance with the original design and inspection requirements or acceptable alternatives
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- Provisions are established that identify mandatory inspection hold points beyond which work may not proceed until inspected by a designated inspector
- The individuals or groups who perform receiving and process verification inspections are identified
- Provisions are established for indirect control by monitoring processing methods, equipment, and personnel if direct inspection is not possible or disadvantageous
- Provisions for both inspection and process monitoring are provided when control is inadequate without both
- Inspection results are documented, evaluated, and their acceptability determined by a responsible individual or group

The TWPC assigns the remaining responsibility for executing inspection activities related to assigned scopes of work to the major subcontractors and suppliers. These activities are performed according to requirements included in procurement documents.

The TWPC line organizations controls this assigned work through the subcontractor assessment/verification process, which includes review, surveillance, audit, and inspection of major subcontractor inspection activities.

4.2.4.2 Acceptance Testing

The TWPC accomplishes acceptance tests as required in support of TWPC operational objectives and waste acceptance activities, including tests prior to installation, preoperational tests, post-maintenance tests, and post-modification tests. This acceptance test practice includes the following elements:

- Required testing demonstrates that the item will perform satisfactorily in service.
 - Required testing activities are identified, documented, and accomplished in accordance with procedures, work instructions, or work orders based on the importance of the testing activities to the item's function and the importance of the item to safety and the TWPC mission.
 - The test requirements and acceptance limits contained in applicable design and procurement documents serve to guide post-installation and post-maintenance testing. Written test procedures include instructions for testing method, equipment and instrumentation, and provisions for the following, as appropriate to the importance of the testing or the item:
 - Calibrated instrumentation
 - Adequate and appropriate equipment, properly maintained
 - Trained, qualified, and licensed, or certified personnel
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- Preparation, condition, and completeness of item to be tested
- Suitable and controlled environmental conditions
- Mandatory inspection hold points for witness by DOE, contractor, or authorized inspector
- Provisions for data collection and storage
- Acceptance and rejection criteria
 - Methods of documenting and recording test data and results
 - A listing of test prerequisites and provisions for assuring test prerequisites have been met
- Identification of precision and accuracy considerations
- The test procedures, work instructions, or work orders prescribe how test results are the documented, evaluated, and accepted by a qualified, responsible individual or group.
- Modifications, repairs, and replacements are tested in a manner similar to the original items or systems, or in an acceptable alternative manner.

The TWPC assigns the responsibilities for executing acceptance test control activities related to assigned scopes of work to major subcontractors and suppliers. These activities are performed according to requirements included in procurement documents.

The TWPC controls this assigned work through the subcontractor assessment/verification process, which includes review, surveillance, and audit of major subcontractor tests and test control activities.

4.2.4.3 Measuring and Test Equipment

The TWPC implements a system for calibration and control of measuring and test equipment in support of items important to the environment, SH&Q and waste acceptance activities. This system includes the following elements:

- Procedures describe the calibration technique and frequency, maintenance, and control of measuring and test instruments, tools, gauges, fixtures, reference and transfer standards, and nondestructive test equipment used in the measurement, inspection, and monitoring of quality-related items. The review and documented concurrence of these procedures is described, and the organizations responsible (including quality assurance) for these functions are identified.
 - Measuring and test equipment is identified and the calibration test data is identified as to the equipment to which it applies.
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**Quality Assurance Program Description**

- Measuring and test equipment is labeled, tagged or otherwise controlled to indicate the due date of the next calibration and/or servicing. The method of otherwise controlling equipment is described.
- Measuring and test instruments are serviced and calibrated at specified intervals based on the required accuracy, purpose, degree of usage, stability characteristics, and other conditions affecting the measurement. The complete status of items under the calibration system is documented and maintained.
- An investigation is conducted and documented to determine the validity of previous inspections performed when measuring and test equipment is found to be out of calibration.
- Calibrating standards have uncertainty (error) requirements of one-fourth to one-tenth of the tolerance of the equipment being calibrated. A greater uncertainty may be acceptable when limited by the state of the art. Calibrating standards have greater accuracy than standards being calibrated. Calibrating standards with the same accuracy may be used if it can be shown as adequate for the requirements and if the basis of acceptance is documented and authorized by responsible line management. The management authorized to perform this function is identified by procedure.
- When measuring and test equipment is found to be out of calibration, measures are taken and documented to determine the validity of previous inspections performed and the acceptability of items inspected or tested since the last calibration. Inspections or tests are repeated on items determined to be suspect.
- Reference and transfer standards are traceable to nationally recognized standards; where national standards do not exist, provisions are established to document the basis for calibration.

The TWPC assigns the remaining responsibilities for executing control of measuring and test equipment related to assigned scopes of work to major subcontractors and suppliers. These activities are performed according to requirements included in procurement documents.

The TWPC line organizations control this assigned work through the subcontractor assessment/verification process, which includes review, surveillance, audit and inspection of major subcontractor measuring and test equipment control activities.



4.3 Assessment

Assessments are planned as part of an integrated process that ensures appropriate oversight, not only for quality assurance, but also in other TWPC program areas such as environment, safety management, emergency management, performance assurance, safeguards and security, and cyber security. Management assessments are the primary tool for oversight of individual areas, and independent assessments are used to provide additional perspective and in-depth evaluations when appropriate. The following describes the application of management assessments and independent assessments with regard to quality assurance.

4.3.1 Management Assessment

The TWPC organizations perform management assessments of quality-related activities for which they are responsible. To accomplish these assessments, the managers review inspection and test results, operating logs, and similar data; perform overview of the work progress and results; and review results of independent assessments performed by the QAM or others. The assessments also evaluate the adequacy and effectiveness of the management system, including identifying and correcting problems that hinder the TWPC from achieving its objectives. To maintain a first hand knowledge of working level conditions and problems, management routinely participates in these management assessments.

Management assessments are a part of the overall assessment/verification process described in Section 4.1.3. When management decides it needs additional data to assess their work, they can use any of the assessment/verification processes identified in Section 4.3.2, "Independent Assessment."

Managers analyze and report the results of individual assessment activities to responsible management.

Management also routinely performs verification activities for their scope(s) of work. These verification activities are described in Section 4.2.2, "Design," and Section 4.2.4, "Inspection and Acceptance Testing."

The TWPC assigns the responsibility for executing management assessment activities related to assigned scopes of work to major subcontractors and suppliers. These activities are performed according to requirements included in procurement documents.

The TWPC controls this assigned work through the subcontractor assessment/verification process, which includes review, surveillance, and audit of major subcontractor management assessment activities.



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4.3.2 Independent Assessment

The QAM independently assesses the adequacy and effectiveness of the QAP. To accomplish these assessments, the QAM reviews objective evidence records that demonstrate the implementation of the TWPC systems and controls to accomplish and document the work. The assessments also evaluate the effectiveness of the systems, including the identification and correction of problems in the course of the work execution. TWPC quality assurance personnel are independent of areas they assess, and their qualifications are documented in accordance with Section 4.1.2, including certification of audit personnel.

To independently assess the overall QAP, the QAM uses the TWPC assessment/verification process described in Section 4.1.3. To implement the assessment/verification process the QAM does the following:

- Prepares quarterly and long-term assessment plans and schedules based on the status, risk, and complexity of work being performed according to the TWPC contract statement of work. Planning and scheduling also takes into account areas of questionable performance, line organization assessment verification data, and line organization and major subcontractor assessment plans and schedules.
 - Conducts the following types of planned and unplanned assessments and formally documents results:
 - Audits
 - Surveillances
 - Document reviews
 - Appraisals
 - Overall annual assessments
 - Focuses on improving items and processes, monitoring work performance, and identifying abnormal performance and precursors of potential problems instead of focusing on individual QAP deviations.
 - Analyzes and reports the results of individual assessment activities to responsible management.
 - Enters assessment results (those requiring follow-up) into the TWPC issues management system so that responsible line management can track findings through closure.
 - Validates and verifies responsible line organization corrective activities necessary for those findings considered deviations.
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- Summarizes QAP feedback data and periodically reports the summarized information to the SH&Q Director and the GM.
- Using data from individual assessments, line organization assessments/verifications, subcontractor assessments/verifications, reportable occurrences, and external (DOE, state, and regulatory agencies) overview activities, annually conducts an overall independent assessment covering the entire scope of QAP.
- Determines and documents overall QAP adequacy and effectiveness, and reports the results to the SH&Q Director and the GM.

The GM provides information from progress and status reports to DOE ORO Program Manager as a part of the normal TWPC reporting process.

The TWPC assigns the responsibilities for executing independent assessment activities related to assigned scopes of work to major subcontractors and suppliers. These activities are performed according to requirements included in procurement documents.

The TWPC controls this assigned work through the subcontractor assessment/verification process, which includes review, surveillance, and audit of the major subcontractor's independent assessment activities.

4.4 Suspect/Counterfeit Items (S/CI) Prevention

4.4.1 The TWPC Quality Assurance Program (QAP) includes the following elements for S/CI prevention:

- Prevents the introduction and use of S/CIs through engineering involvement, design, procurement, testing, inspection, maintenance, evaluation, disposition, reporting, trend analysis, and lessons learned work process controls described throughout this QAPD.
- Trains and informs selected managers, supervisors, and workers on S/CI processes and controls (including prevention, detection, and disposition of S/CIs) in accordance with Section 4.1.2 of this QAPD.
- Identifies and disposes of S/CIs onsite using the nonconformance controls identified in Section 4.1.3 of this QAPD.
- Restricts S/CI use to only those items that have been found acceptable through engineering analysis and formal disposition process.
- Collects, maintains, disseminates, and uses the most accurate, up-to-date information on S/CIs and associated suppliers using all available sources.
- Identifies the management point of contact responsible for S/CI to ensure that the DOE Office of Environment, Safety and Health has a viable recipient for S/CI information notices.

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4.4.2 In addition to the QAP elements above, controls are included using available S/CI information as follows:

- Engineering is involved in the development of procurement specifications; inspection and testing; and when replacing, maintaining, or modifying equipment.
- Procurement processes identify technical and QA requirements in procurement specifications to prevent introduction of S/CIs.
- Receipt inspections accept only those items that comply with the procurement specifications consensus standards, and commonly accepted industry practices
- Inspection, identification, evaluation, and disposition of S/CIs installed in all safety applications and other applications that create potential hazards.
- Engineering evaluates and disposes any S/CIs installed in safety applications/systems or in applications that create potential hazards. The evaluations consider potential risks to the public and worker, cost/benefit impact, and include a schedule for replacement (if required).
- S/CIs identified in non-safety applications during routine maintenance and/or inspections are reported, evaluated, and dispositioned using TWPC approved procedures to prevent future use in safety applications.
- The DOE Inspector General (IG) is contacted before destroying or disposing of S/CIs and their documentation to determine whether to retain them for criminal investigation or litigation.
- Procured or installed S/CIs are tested as necessary using approved engineering test methods.
- S/CIs are reported per DOE O 231.1A, Environment, Safety, and Health Reporting, and DOE O 221.1, Reporting Fraud, Waste, and Abuse.
- Lessons learned reports are issued for use in improving the S/CI prevention.

4.5 Software Quality Assurance

4.5.1 Software in use at the TWPC is controlled and evaluated to determine whether it is business related software or safety software. TWPC safety software applicable to Structures, Systems or Components (SSC's) is classified as defined in 10 CFR 830, procured, controlled, evaluated and maintained in accordance with DOE O 414.1C, DOE G 414.1-4, and ASME NQA-1, 2000. The following software quality assurance attributes and activities are applied as applicable to safety software:

- Software project management and quality planning.
- Software risk management



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- Software configuration management
- Procurement and supplier management
- Software requirements identification and management
- Software design and implementation
- Software safety
- Verification and validation
- Problem reporting and corrective action
- Training of personnel in the design, development, use and evaluation of software.

4.5.2 Safety software requirements and responsibilities are identified and implemented through this QAPD and TWPC procedures that include:

- The grading of software
- Performing safety reviews
- Developing procurement controls for acquisition of computer software
- Applying SQA requirements to software life cycles
- Documenting and tracking customer requirements
- Managing software configuration throughout the life cycle
- Performing verification and validation
- Training personnel in the design, development, use and evaluation of safety software.

5.0 QUALITY ASSURANCE PROGRAM DEFINING AND IMPLEMENTING DOCUMENTS

The TWPC QAP defining and implementing documents are integrated with the overall TWPC management control system.

An implementing document matrix relates the 10 CFR 830 Quality Assurance requirements and DOE O 414.1C (identified in Section 2) and the TWPC's implementing documents. The current matrix is provided in Appendix A. Implementing documents are prepared and implemented to support work according to the TWPC contracted Statement of Work. Waste acceptance or other activities requiring activity-specific quality plans incorporate activity-specific matrices of implementing documents.



6.0 IMPLEMENTATION STRATEGY

To implement the program described in this QAPD, the TWPC performs the following:

- Prepares and maintains policies, plans, and procedures to meet TWPC requirements as appropriate to the phased work activity and schedule
- Staffs, trains, and qualifies TWPC personnel
- Includes applicable TWPC requirements in procurement documents for major subcontractors and suppliers that will be responsible and liable for their work scope (those using their own QAP and procedures)
- Evaluates and accepts major subcontractor and supplier QAPs before they perform quality related work
- Completes other preparations required to implement quality-assuring activities as appropriate to the phased work activity and schedule (e.g., develops mechanisms for implementing procedures, e.g., files, records systems, equipment, supplies, etc.)

Applicable QAP controls are implemented as appropriate to the phased work activity and schedule and prior to performing quality affecting functions within the particular TWPC work activities.

7.0 DEFINITIONS

- a. Assessment/Verification – The act of reviewing, inspecting, testing, checking, conducting surveillances, auditing, or otherwise determining and documenting whether items, processes, or services meet specified requirements. The terms assessment and verification, as used in DOE Order 414.1C, are synonymous; their use is determined by who is performing the work. Assessments are performed by or for senior management. Verifications are preformed by the line organization.
- b. Deviation – As used in the QAP, "deviation" means a departure from a specified requirement. A deviation can be a condition in which characteristics of an activity or service do not conform to prescribed limits; a document that is not available or is inadequate; or a procedure that does not yield the desired results. These conditions can occur at any point in designing, constructing, handling, shipping, storing, installing, producing or operating an item or process; performing a service; or executing quality assurance activities.
- c. Overview – An inclusive term that includes the act of assessing and verifying as defined above.
- d. Quality (10 CFR 830) – The condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.



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- e. Quality Assurance (10 CFR 830) – All those actions that provide confidence that quality is achieved.
- f. Quality Assurance (ASME NQA-1) – All those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.
- g. Quality-related – The composite of activities intended to achieve quality and those intended to assure the achievement of quality.
- h. Quality Assurance Program (QAP) – The overall program established by an organization to implement the TWPC quality assurance requirements. QAPs shall be documented and describe the management system, including planning, scheduling, and cost control considerations.

For consistency in communicating, the overall QAP for the TWPC will be referred to as the “TRU Waste Processing Center Quality Assurance Program,” or simply as the “QAP.” This umbrella QAP is expected to consist of this document and the following subcomponent programs:

- Major subcontractor/supplier QAPs
- TWPC QAPs for waste acceptance
 - T-CM-FW-A-QP-003, QAP for Certification and Acceptance of Waste at NTS
- i. Quality Assurance Program Description (QAPD) – A program-defining document containing, at a minimum, the identification of the scope of work to which the QAP is to be applied, the scope of quality-assuring activities to be applied and implemented, the organizational responsibilities and authorities for implementing the quality-assuring activities, and the procedures to be used in implementing those activities.
- j. Significant Condition Adverse to Quality – A deviation from programmatic requirements which causes or can potentially cause a significant negative impact. Significant conditions (deviations) are described below:
 - The deviation requires extensive redesign, repair, or rework
 - The deviation has substantial generic implications at other DOE facilities
 - The deviation is a falsification of records



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- The deviation is a deliberate failure to follow procedures
 - The deviation has occurred repeatedly such as to reasonably indicate an adverse trend or programmatic failure of a substantial nature
 - k. Waste Acceptance Activities – Those activities related to the integrity of the waste product so that it meets waste acceptance criteria of the applicable disposal facility.
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Appendix A: Requirements of DOE Order 414.1C, 10 CFR 830.122, and TWPC Implementing Documents			
Quality Assurance Criteria	Requirement	Document Number	Implementing Document
1	Management		
1(i)	Program	CH-P-AD-006	WIPP Graded Approach
		CM-A-AD-001	Safety Management System Description Plan
		CM-A-AD-004	Project Management Plan
		CM-P-AD-036	Change Management
		CM-P-AD-039	Graded Approach
		CM-A-IS-001	Operations Environment, Health, and Safety Plan
		CM-A-QP-001	Quality Assurance Program Description
		LL-A-OP-004	Mixed Low Level Waste/Low Level Waste Analysis Plan
		LL-A-OP-007	Mixed Low Level Waste/Low Level Waste Process Control Program
		LL-A-OP-008	NTSWAC, Mixed Low Level Waste/Low Level Waste Implementation Crosswalk (NIC)
		LL-A-OP-009	Mixed Low Level Waste/Low Level Waste Characterization Plan
		LL-A-QP-001	Quality Assurance Plan for Certification and Acceptance of Mixed Low Level Waste/Low Level Waste at the Nevada Test Site
		CH-P-AD-013	Software Quality Assurance



Appendix A: Requirements of DOE Order 414.1C, 10 CFR 830.122, and TWPC Implementing Documents			
Quality Assurance Criteria	Requirement	Document Number	Implementing Document
1(ii)	Personnel Training and Qualification	CM-P-EG-009 CH-P-OP-020 CM-A-AD-003 CM-P-AD-027 CM-P-AD-064 CM-P-IS-003 CM-P-RP-316 CM-P-RP-317	Training in Engineering Procedures Operations Training Program Description Training Program Personnel Qualification and Training Obtaining Exceptions to TWPC Training Requirements General Employee and Visitor Training Radiological Worker Training Radiological Control Technician Training
1(iii)	Quality Improvement	CH-P-AD-044 CM-P-AD-038 CM-P-AD-041 CM-P-AD-042 CM-P-AD-043 CM-P-AD-046 CM-P-AD-047 CM-P-AD-048 CM-P-IS-009 CM-P-IS-015	Waste Corrective Action and Nonconformances Occurrence Reporting Nonconformance Control Corrective Action Work Suspension and Restart Lessons Learned Evaluation and Reporting of Potential PAAA Noncompliances Issues Tracking Inspections Incident Reporting and Investigation



Appendix A: Requirements of DOE Order 414.1C, 10 CFR 830.122, and TWPC Implementing Documents				
Quality Assurance Criteria	Requirement	Document Number	Implementing Document	
1(iv)	Documents and Records	CM-P-AD-035 CM-P-AD-049 CM-P-AD-059 CM-P AD-061 CM-P-IS-011 CM-P-RP-320 CM-P-RP-321	Subcontractor Document Control Records Management Controlled Document Distribution Document Preparation, Review, and Approval EHS Recordkeeping Dose Reporting and Records Radiological Protection Records	
2	Performance			
2 (i)	Work Processes	CH-P-AD-045 CH-P-OP-001 CH-P-OP-002 CH-P-OP-003 CH-P-OP-004 CH-P-OP-005 CH-P-OP-006 CH-P-OP-008 CH-P-OP-009 CH-P-OP-010 CH-P-OP-011 CH-P-OP-013	Waste Program Data Validation Receipt of CH Solid Waste to CHSA CHSA Operations Box Breakdown Area Operations Glove Box Operations F-213 Filter Replacement Return Transfer to DOE BBA and GB dP Requirements/Verification Breathing Air Compressor System Water Mist Fire Protection System Drum Bag In/Bag Out & Glove Ports Visual Examination Technique	
2(i)	Work Processes (Cont)	CH-P-OP-014	CH Waste and Activity Inventory Control	



Appendix A: Requirements of DOE Order 414.1C, 10 CFR 830.122, and TWPC Implementing Documents			
Quality Assurance Criteria	Requirement	Document Number	Implementing Document
		CH-P-OP-015	Temperature Data Logger Operation
		CH-P-OP-021	Visual Examination to Confirm Radiography
		CH-P-OP-022	Non-Compliant Containers
		CH-P-OP-030	Visual Examination in Lieu of Radiography
		CH-P-MT-401	Hot Cell Box Breakdown Area Supply & Exhaust Blower Preventive Maintenance
		CH-P-MT-402	Glovebox Preventive Maintenance
		CH-P-MT-403	BBA Enclosure Preventive Maintenance
		CH-P-MT-404	Contact Handled Waste Scales Preventive Maintenance
		CH-P-MT-405	Breathing Air Compressor Preventive Maintenance
		CH-P-MT-406	Preventive Maintenance of Water Mist Fire Protection System
		CH-P-MT-410	Glove Box Station 1 Drum Crusher Preventive Maintenance
		CH-P-MT-411	Glove Box Station 5 Waste Compactor Preventive Maintenance
		T-CH-252-P-OP-100	DWAS IPAN Operations Procedure & Data Validation
		T-CH-252-P-OP-103	Operating the Mobile Segmented Gamma Scanner
		T-CH-252-P-OP-201	Radiography Screening Procedure for Prohibited Items
		T-CH-252-P-OP-202	Radiographic Test and Training Drum Requirements
		T-CH-253-P-OP-300	Headspace Gas Sampling and Analysis
		T-CH-253-P-OP-301	GC/MS Calibration and System Maintenance
		T-CH-253-P-OP-302	Assembly of Headspace Gas Batch Data Reports
2(i)	Work Processes (Cont)	T-CH-253-P-OP-303	Installation of Sample Ports



Appendix A: Requirements of DOE Order 414.1C, 10 CFR 830.122, and TWPC Implementing Documents			
Quality Assurance Criteria	Requirement	Document Number	Implementing Document
		T-CH-253-P-OP-304	Data Generation Level Review and Approval of Headspace Gas Batch Data Reports
		T-CH-253-P-OP-305	Headspace Gas Performance Demonstration Program (PDP) Testing
		T-CH-270-P-OP-001	Acceptable Knowledge Process
		CM-A-AD-001	Safety Management System Description
		CM-A-AD-004	Project Management Plan
		CM-A-AD-011	Configuration Management Program
		CM-A-EG-004	Safety Significant Structures, Systems and Components
		CM-M-EM-100	Local Emergency Manual (LEM)
		CM-A-IS-001	Worker Health and Safety Program
		CM-A-MT-001	Reliability Assurance Program Description
		CM-A-RP-002	Radiation Protection Program Implementation Plan
		CM-A-RP-004	Implementation of Radiation Protection Practices
		CM-A-MT-002	Preventive Maintenance Plan
		CM-A-MT-003	Corrective Maintenance Plan
		CM-P-AD-037	Unreviewed Safety Question Process
		CM-P-AD-061	Document Preparation, Review, and Approval
		CM-P-IS-001	Light Vehicle Operation
		CM-P-IS-002	Equipment Operation
2(i)	Work Processes (Cont)	CM-P-IS-004	Hazard Communication
		CM-P-IS-005	Compressed Gases



Appendix A: Requirements of DOE Order 414.1C, 10 CFR 830.122, and TWPC Implementing Documents				
Quality Assurance Criteria	Requirement	Document Number	Implementing Document	
		CM-P-IS-006	Safety/Committee Meetings	
		CM-P-IS-007	Activity Hazards Analysis	
		CM-P-IS-008	Electrical Safety	
		CM-P-IS-009	Inspections	
		CM-P-IS-010	Industrial Hygiene Monitoring	
		CM-P-IS-012	Powered Industrial Trucks	
		CM-P-IS-013	Medical Services and Bloodborne Pathogens Program	
		CM-P-IS-014	Posting and Labeling	
		CM-P-IS-016	Materials Handling	
		CM-P-IS-017	Personal Protective Equipment	
		CM-P-IS-018	Fire Prevention	
		CM-P-IS-019	Lock Out/Tag Out	
		CM-P-IS-021	Hot Work	
		CM-P-IS-022	Confined Space Entry	
		CM-P-IS-023	Scaffolding	
		CM-P-IS-024	Fall Protection	
		CM-P-IS-025	Hoisting & Rigging	
		CM-P-IS-026	Hearing Conservation	
2(i)	Work Processes (Cont)	CM-P-IS-027	Respiratory Protection	
		CM-P-IS-039	Hand & Portable Power Tools	
		CM-P-MT-001	Preventive Maintenance of Idle Equipment	



Appendix A: Requirements of DOE Order 414.1C, 10 CFR 830.122, and TWPC Implementing Documents			
Quality Assurance Criteria	Requirement	Document Number	Implementing Document
		CM-P-MT-003	Waste Processing Facility Building and Structure Preventive Maintenance
		CM-P-MT-005	Hoists, Cranes, and Rigging Preventive Maintenance
		CM-P-MT-007	Post Maintenance/Extended Downtime Insulation Resistance Testing
		CM-P-MT-012	Emergency Equipment Preventive Maintenance
		CM-P-MT-506	Main Building Ventilation System Preventive Maintenance
		CM-P-MT-512	Fire Detection and Suppression System Preventive Maintenance
		CM-P-OP-010	Waste Processing Facility Conduct of Operations
		CM-P-OP-011	Programmable Logic Controller and Human Machine Interface Operations
		CM-P-OP-012	Employee Notification System
		CM-P-EM-100	Emergency Events
		CM-P-EM-101	Atypical Events
		CM-P-EM-102	Conduct of Drills
		CM-P-OP-404	Waste Transportation
		CM-P-OP-406	Verification and Validation Guidance for Operations Procedures
		CM-P-OP-407	Temporary Modifications
2(i)	Work Processes (Cont)	CM-P-QA-016	Control of Measuring and Test Equipment
		CM-P-RP-301	External Dosimetry Program
		CM-P-RP-302	Internal Dosimetry Program
		CM-P-RP-305	Sealed Radioactive Source Control



Appendix A: Requirements of DOE Order 414.1C, 10 CFR 830.122, and TWPC Implementing Documents				
Quality Assurance Criteria	Requirement	Document Number	Implementing Document	
		CM-P-RP-306	Radiation / Contamination Surveys	
		CM-P-RP-307	Radiological Air Monitoring	
		CM-P-RP-309	Environmental Permits –Inspections/Monitoring and Reporting	
		CM-P-RP-310	DOT Shipment Surveys	
		CM-P-RP-312	Instrument Use, Calibration, and Daily Checks	
		CM-P-RP-313	Radiological Work Permits	
		CM-P-RP-314	Personnel Decontamination and Skin Dose Calculations	
		CM-P-RP-318	As Low As Reasonably Achievable (ALARA) Program	
		CM-P-RP-319	Radiological Posting and Labeling	
		CM-P-RP-322	Contamination Control	
		CM-P-RP-324	Operation of the Personnel Contamination Monitor	
		CM-P-RP-325	Beta Continuous Air Monitor Operation	
		CM-P-RP-326	Area Radiation Monitor Operation	
		CM-P-RP-327	Low Background Counter Operation	
		CM-P-RP-328	Operation of the Alpha/Beta Smear Counter	
		CM-P-RP-329	Electronic Dosimetry System Operation	
2(i)	Work Processes (Cont)	CM-P-RP-330	Alpha Continuous Air Monitor Operation	
		CM-P-RP-331	Radnet Operation	
		LL-A-OP-005	NTS WAC, Rev. 6, Low Level Waste Profile	
		LL-A-OP-006	Mixed Low Level Waste/Low Level Waste Verification and Certification	



Appendix A: Requirements of DOE Order 414.1C, 10 CFR 830.122, and TWPC Implementing Documents				
Quality Assurance Criteria	Requirement	Document Number	Implementing Document	
		UT-P-OP-500	Environmental Chill Water System and Air Handling Units	
		UT-P-OP-501	Process Chill Water System	
		UT-P-OP-502	Plant and Instrument Air System	
		UT-P-OP-503	Water Supply System	
		UT-P-OP-505	Diesel Generator System	
		UT-P-OP-506	Main Building Ventilation and HEPA System	
		UT-P-OP-507	Uninterruptible Power Supply	
		UT-P-OP-508	Heating, Ventilation, and Air Conditioning Duct Heaters	
		UT-P-OP-509	Vertical Reciprocating Conveyor Operation	
		UT-P-OP-511	Motor Control Center Operations and Electrical Distribution	
		UT-P-OP-512	Fire Suppression System	
		UT-P-OP-516	Main Building Ventilation HEPA Filter Changeout	
		UT-P-MT-505	Diesel Generator Preventive Maintenance	
		UT-P-MT-507	Uninterruptible Power Supply Preventive Maintenance	
2(ii)	Design	CM-P-EG-001	General Procedure for Professional Activities	
		CM-P-EG-002	Engineering Interface	
		CM-P-EG-003	Developing and Issuing Engineering Documents	
		CM-P-EG-005	Design Classification Levels and Project Engineering Reviews	
		CM-P-EG-006	Preparation of Calculations	
		CM-P-EG-007	Design Verification	
		CM-P-EG-008	Record Drawings	



Appendix A: Requirements of DOE Order 414.1C, 10 CFR 830.122, and TWPC Implementing Documents			
Quality Assurance Criteria	Requirement	Document Number	Implementing Document
2(iii)	Procurement	CM-P-PC-002 CM-P-PC-401 CM-P-PC-402 CM-P-PC-403 CM-P-PC-404 CH-P-PC-001 CM-P-AD-035	Procurement of Items and Services Acquisition Planning Solicitation Evaluation Procurement Administration Procurement Closeout Procurement of Waste Items and Services Subcontract Document Control
2(iv)	Inspection and Acceptance Testing	CM-P-QA-004	Material Receipt Inspection
3	Assessment		
3(i)	Management Assessment	CM-P-AD-060	Management Assessment
3(ii)	Independent Assessment	CM-P-QA-005	Surveillances
		CM-P-QA-018	Assessment Planning
		CM-P-QA-020	Independent Assessment
4	Suspect/Counterfeit Items	CM-P-QA-004	Material Receipt Inspection
5	Software Quality Assurance	CM-P-AD-064	Software Quality Assurance



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